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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/690,772	10/22/2003	Christopher M. Kim	CKIM 3.0-001 DIV	6954

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EXAMINER	
ROONEY, NORA MAUREEN	
ART UNIT	PAPER NUMBER
1644	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/690,772	KIM, CHRISTOPHER M.	
	Examiner	Art Unit	
	Nora M. Rooney	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/22/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-12 are pending.

2. Claims 1-12 are under examination as they read on a pharmaceutical compound comprising a therapeutically effective amount of bee venom and an anesthetic. Upon further consideration, the species requirement of 09/25/2006 has been withdrawn.

3. Applicant's IDS filed on 10/22/2003 is acknowledged. The declaration cited on the IDS has been considered but was crossed off by the Examiner because it is not an appropriate publication for an IDS.

Claim Objections

4. Claims 1-12 are objected to because of the following informalities:

Claims 6-8 and 11 lack spaces between the number and the unit of measure. For example ".1mg" should be changed to ".1 mg".

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-9 and 11-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Steigerwaldt et al. (Reference CD on the IDS filed 10/22/2003, entire document).

Steigerwaldt et al. teaches a pharmaceutical composition comprising bee venom and an anesthetic administered as a therapy for rheumatoid arthritis (In particular, page 1047, left column second to last paragraph to second to last paragraph in right column). Specifically, the bee venom (between .06 and 1.62 mg per injection with 4.8 mg total given in 8 injections) and a local anesthetic (.2% procaine hydrochloride) were given simultaneously in a therapeutically effective amount to 50 patients by intradermal injection in a liquid carrier.

Claim 2 is included in this rejection because the ratio of .2 mg procaine to .06 mg, .18 mg, .54 mg and 1.62 mg of bee venom in each injection is within the range of about 20:1 to 1:10.

Claim 3 is included in this rejection because the ratio of .2 mg procaine to .06 mg, .18 mg and .54 mg of bee venom in each injection is within the range of about 10:1 to 1:5.

Claim 4 is included in this rejection because the ratio of .2 mg procaine to .06 mg and .18 mg of bee venom in each injection is within the range of about 3:1 to 1:1.

Claim 6 is included in this rejection because injections of .06 mg, 1.62 mg and 4.8 mg are "about .1mg to about 10 mg."

Claim 7 is included in this rejection because .06 mg of bee venom in 1 cc of liquid carrier is .6 mg/ml and is "about 0.5 mg and about 5.0 mg of bee venom per ml."

Claim 8 is included in this rejection because .18 mg of bee venom in 1 cc of liquid carrier is 1.8 mg/ml. Injections of .6 mg /ml and 1.8 mg /ml is "about 1 mg of bee venom per ml."

Claims 11 and 12 are included in this rejection because injections of .06 mg,1.62 mg and 4.8 mg are "about .1mg to about 10 mg" and because standardized bee venom preparation produced by filtering the preparation through a 25-micron filter adds no patentable weight since the been venom preparation of Steigerwaldt et al. is for in vivo use and is inherently sterilized and purified for pharmaceutical use.

Determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (Claim was directed to a novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive pre-reacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product.).

The reference teachings anticipate the claimed invention.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Steigerwaldt et al. (IDS, entire document), in view of Simics (Reference U on PTO-892, entire document).

Steigerwaldt et al. teaches the therapeutic use of bee venom and a local anesthetic as discussed *supra*.

The claimed invention differs from the prior art by the recitation of using lidocaine as the local anesthetic.

Simics et al. teaches a pharmaceutical composition comprising bee venom solution mixed with xylocaine or lidocaine to desensitize the affected area of injection because bee venom injection therapy alone may cause pain (In particular, see entire document and page 108, question 10).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to substitute the local anesthetic taught by Simics et al. with the local anesthetic as taught by Steigerwaldt et al to obtain a pharmaceutical composition comprising bee venom and lidocaine.

One ordinary skill in the art at the time the invention was made would have been motivated to substitute local anesthetics because the Simics et al. reference teaches

that lidocaine works to reduce injection site pain. The strongest rationale for combining references is a recognition, expressly or impliedly in the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent, that some advantage or expected beneficial result would have been produced by their combination. In re Semaker. 217 USPQ 1, 5 - 6 (Fed. Cir. 1983). See MPEP 2144.

From the reference teachings, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of evidence to the contrary.

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nora M. Rooney whose telephone number is (571) 272-9937. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

December 21, 2006

Nora M. Rooney, M.S., J.D.
Patent Examiner
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MICHAIL BELYAVSKYI, PH.D.
PATENT EXAMINER
12/26/06